SUPPORT FOR THE AMENDMENTS

Support for the amendment of Claim 1 is found in original claim 7 and on page 5, lines 8-14, in the specification.

Claims 3-7 are herein canceled.

No new matter will be added to this application by entry of this amendment.

Upon entry of this amendment, Claims 1 and 8-12 are active.

REMARKS/ARGUMENTS

Applicants have described that Pantethine is known to be hygroscopic and therefore conventional powder forms are difficult to maintain and handle for the manufacture of solid dosage forms of medicaments such as, for example, tablets or capsules. For this reason pantethine is conventionally supplied as a viscous liquid for use in preparation of solid dosage forms. The claimed invention is directed to a pantethine particulate which is free flowing, does not agglomerate, is stable in storage, can be easily manufactured, and is therefore suitable for use in the formulation and preparation of solid dosage forms of medicaments.

The claimed invention provides a particulate comprising: pantethine, a light anhydrous silicic acid and a microcrystalline cellulose, which is stable in storage and has good particle flow properties. Applicants note that Claim 1 is herein amended to include the description: a weight ratio of light anhydrous silicic acid to microcrystalline cellulose in the total content of these two substances is in a range from about 2/1 to about 4/1 per 1 weight part of pantethine.

Applicants also note that Claims 3-7 are herein canceled. The following addresses the rejections as stated in the Official Action of October 22, 2008.

Applicants also further note that "particulate" as defined in the Merriam Webster's Collegiate Dictionary (Tenth Edition) is "of or relating to separate minute particles." As described in the present application the particulate of the claimed invention is a stable, free flowing concentrate form of pantethine which can be used to prepare a tablet, capsule or other solid dosage form according to conventional methods. No such particulate is disclosed or suggested in the cited references.

Applicants have shown in Tables 3 and 4 of the specification that the particulates according to the claimed invention have significantly improved flow properties and little or no decrease in pantethine content even after 1 month of storage at 50°C. For example, Formulation 2, according to the claimed invention, is shown to have excellent flowability in Table 3 and in Table 4, retention of pantethine (97.7 to 97.0) is significantly improved. In contrast, as can be seen in Table 4, the particulate of Formulation 1, prepared from the claimed ingredients but not having the claimed composition has poor stability of pantethine content (96.9 to 93.9).

The rejection of Claims 1-7 under 35 U.S.C. 103(a) over Murakami is respectfully traversed.

Murakami is directed to a compression molded form such as a tablet (Claim 13) which rapidly disintegrates in the oral cavity. The composition contains an excipient, **erythritol**, a medicinal agent and various agents used for the manufacture of a tablet such as a lubricant, a disintegrator, a binder, colorant and surface active agent, as examples.

The Office acknowledges that Murakami teaches a compression molded material (Official Action dated October 22, 2008, page 4, line 1), which according to the definition above cannot be a particulate as according to the claimed invention.

Applicants respectfully note that the U.S. Court of Customs and Patent Appeals has stated (*In re Pearson*, 494 F2d. 1399, 181 USPQ 641 (C.C.P.A. 1974)):

> We do not mean to imply that terms which recite the intended use or a property of a composition can never be used to distinguish a new from an old composition. . . . such terms must define, indirectly at least, some characteristic not found in the old composition.

Applicants respectfully submit that nowhere does Murakami disclose or suggest a particulate material. Rather, this reference describes the formation of a particular solid dosage form. Erythritol is a necessary component of the reference composition.

Applicants note that in a Precedential Opinion rendered by the Board of Patent Appeals and Interferences (Ex parte Whalen II, Appeal 2007-4423, p. 16, lines 5-9, decided July 23, 2008), the Board stated:

> The KSR Court [KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007)] noted that obviousness cannot be proven merely by showing that the elements of a claimed device were known in the prior art; **it must be shown that those of ordinary skill in the art would have had some "apparent reason to combine the known elements in the fashion claimed**." (Bold added)

Applicants respectfully submit that the Office has not reasonably explained how or why a person of ordinary skill in the art, at the time of the invention, would have obtained the claimed invention, based on the disclosure of the cited reference. Murakami requires erythritol, a sweetener, which is freely soluble in water. The Murakami composition requires up to 99% excipient and erythritol by weight (Col. 5, lines33-34) and the erythritol is present in equal or greater amount (Col. 5, lines 39-42). The Office has not explained why one of ordinary skill in the art, at the time of the invention would have eliminated erythritol from the compression molded tablet of the reference and replaced it with the components of the claimed composition to obtain the particulate of the present invention. Therefore, Applicants respectfully submit that the Office has not met its burden to show a prima facie case of obviousness.

Moreover, Murakami is directed to the production of a quickly disintegratible compression-molded material, which has properties such as sufficient hardness, speedy disintegration and solubility (Col. 4, lines 6-17), whereas the claimed invention is directed to a particulate which is free-flowing and stable. The reference is not directed to the same field of endeavor, does not deal with the same problem and is therefore nonanalogous to the claimed invention. Therefore, Applicants respectfully submit that one of ordinary skill in the art would not have been motivated, at the time of invention to derive the claimed invention based on the description of the cited reference.

For all the above reasons, Applicants respectfully submit that the cited reference cannot render the claimed invention obvious and withdrawal of the rejection Claims 1-7 under 35 U.S.C. 103(a) over Murakami is respectfully requested.

The rejection of Claims 1 and 3-12 under 35 U.S.C. 103(a) over Murakami is respectfully traversed.

The primary deficiency of this reference relative to Claim 1 of the present invention is described above. Claims 3-12 all depend directly or indirectly from Claim 1. The reference cannot cure its own deficiency and therefore, Applicants respectfully submit that it cannot render the claimed invention obvious.

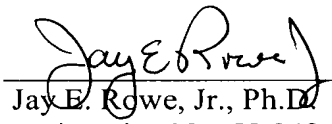
Withdrawal of rejection of Claims 1 and 3-12 under 35 U.S.C. 103(a) over Murakami is therefore respectfully requested.

The rejection of Claims 1 and 3-12 under 35 U.S.C. 112, first paragraph, is believed obviated by appropriate amendment. Claim 1 is herein amended to include descriptive wording from Claim 7 and the specification as originally filed. Accordingly, the amended claim does not include new matter. Accordingly, withdrawal of the rejection of Claims 1 and 3-12 under 35 U.S.C. 112, first paragraph, is respectfully requested.

Applicants respectfully submit that the above-identified application is in condition for allowance and early notice of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Jay E. Rowe, Jr., Ph.D.
Registration No. 58,948

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/07)